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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,905	08/06/2003	Weiniu Gan	CL001147DIV	8380

25748 7590 05/31/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
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EXAMINER

HADDAD, MAHER M

ART UNIT PAPER NUMBER

1644

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/634,905	Applicant(s) GAN ET AL.	
	Examiner Maher M. Haddad	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 15-29 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 15-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment I</u> . |

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DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Maher Haddad, Art Unit 1644, Technology Center 1600.

2. Claims 1-3 and 15-29 are pending.

3. Applicant's election with traverse of Group II, claim 3(now claims 3 and 15-27) drawn to an antibody that binds to SEQ ID NO:2 filed on 3/28/06, is acknowledged.

Applicant's traversal is on the grounds that examination of Group II inherently includes a search of the amino acid sequence of the polypeptides claimed in Group I. This is not found persuasive because the specific antibodies/polypeptide are recognized divergent subject matter. In addition, the polypeptides and antibodies are distinct because their structures are different and are therefore capable of separate manufacture, use and sale. Therefore these products are distinct and independent, and searches of all groups would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 1-2 and 28-29 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

5. Claims 3 and 15-27 are under examination as they read on an antibody that binds to SEQ ID NO: 2.

6. The specification on page 1 should be amended to reflect the status of 09/819,607 and the relationship between 09/816,095 and the instant application.

7. Claims 26-27 are objected to because it is improper to recite "an Fab", "an F(ab')₂" and "an Fv". It is suggested that word "an" be change with "a".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

The phrase "a composition comprising the antibody of claim 3/15/16/17 and a pharmaceutically acceptable carrier" claimed in claims 22-25 represent a departure from the specification and the claims as originally filed.

Applicant's amendment filed 3/28/06 does not point to the specification for support for the newly added limitation "a composition comprising the antibody of claim 3/15/16/17 and a pharmaceutically acceptable carrier" as claimed in claims 22-25. However, the specification does not provide a clear support such limitations. The instant claims now recite limitations which were not clearly disclosed in the specification and recited in the claims as originally filed.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiki et al. (Biochem. Biophys. Res. Commun. 255:182-187, 1999), in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1).

The claims are drawn to various forms of an antibody which specifically binds to a polypeptide of SEQ ID NO:2.

Seiki et al. teach a rat sequence of glucuronyltransferase-S, GlcAT-S that is involved in the biosynthesis of the HNK-1 carbohydrate epitope (see entire document, e.g., Fig. 1 and 2). The GlcAT-S polypeptide has 89.5% identity to the polypeptide of claimed SEQ ID NO:2 (see attached sequence alignment in particular). In addition to having 89.5 identity, the GlcAT-S

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polypeptide and claimed SEQ ID NO:2 share a transmembrane region (RFFILLPWILIVIIMLDVD) and four highly conserved regions, named motifs at:

- I. LPTIYAITPTYSRPVQKAELTRLANTFRQVAQLHWILVED,
- II. FADDDNTYSLELFQEMRTTRKVSVPVGLVG,
- III. GWREDRPF AIDMAGFAVSLQVILSNPKAVFKRRGSQPGMQE, and
- IV. LEPKANNTCKVLVWHTRTEKVN.

Also, Seiki et al teaches several stretches of amino acid identity that are 5 amino acids in length or greater (see Fig. 2 in particular).

Seiki et al. do not teach antibodies to the GlcAT-S polypeptide, or to the polypeptide of claimed SEQ ID NO:2 as claimed in claims 3 and 15-17.

However, Campbell teaches that it is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (see page 3 figure 11.1 in particular). One field of research in which monoclonal antibodies may prove of particular value is in the study of chromosomal proteins. The search for those chromosomal proteins which are responsible for determining cell phenotype has been particularly long and comparatively fruitless and monoclonal antibodies are ideal tools for the dissection of the complex mixture of proteins. As hybridoma production becomes a more routine laboratory technique (see page 29 and 30 under Basic research in particular).

Further, it has been held that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies. Ex parte Erlich, 3 USPQ2d 1011, 1015 (BPAI 1986).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a monoclonal antibody as taught by Campbell against the GlcAT-S polypeptide, the transmembrane region, motifs or any stretches of amino acid identity that are 5 amino acids in length or greater that are shared with claimed SEQ ID NO:2 taught by the Gasser et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because it was customary at the time the invention was made to make monoclonals against any new macromolecule as taught by Campbell.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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12. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiki et al. (Biochem. Biophys. Res. Commun. 255:182-187, 1999), in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1) as applied to claims 3 and 15-17 above and further in view of US. Pat. No. 6,593,119.

The teachings of Seiki et. al. and Campbell have been discussed previously.

The claimed invention differs from the reference teachings only by the recitation the antibody is coupled to a detectable substance in claims 18-21.

The '119 patent teaches that antibodies having specificity against an epitope of a Core 2c GlcNAc-T Polypeptide, or a Core 2c GlcNAc-T Related Polypeptide. Antibodies may be labeled with a detectable substance and used to detect polypeptides of the invention in biological samples, tissues, and cells (see col. 3 lines 46-51 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple the resultant antibodies as taught by Seiko et al. in view of Campbell with detectable substance as taught by the '119 patent.

The ordinary artisan at the time the invention was made would have been motivated to do so for the use to detect the claimed polypeptides in biological samples, tissues, and cells as taught by the '119 patent.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

13. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiki et al. (Biochem. Biophys. Res. Commun. 255:182-187, 1999), in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1) as applied to claims 3 and 15-17 above and further in view of Harlow et.al. (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1988).

The teachings of Seiki et. al. and Campbell have been discussed previously.

The claimed invention differs from the reference teachings only by the recitation of a composition comprising the antibody in claims 22-25.

Harlow et.al. teach that phosphate buffered saline (PBS) or similar isotonic solutions are commonly used buffers for storing purified antibodies (see in particular page 287, storing purified antibodies).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the resultant antibodies as taught by Seiko et al. in view of Campbell with PBS as taught by Harlow et al. which would inherently be a composition that could be used for storing the antibody.

The ordinary artisan at the time the invention was made would have been motivated to combine the resultant antibodies with PBS which inherently would be a composition, because PBS is a commonly used buffer to store purified antibodies as taught by Harlow et al.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

14. Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seiki et al. (Biochem. Biophys. Res. Commun. 255:182-187, 1999), in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1) and in further view of Owens et al.

The teachings of Seiki et. al. and Campbell have been discussed, *supra*.

The claimed invention differs from the reference teachings only by the recitation of an antibody fragment such as a Fab fragment, A F(ab')₂ fragment, or Fv fragment in claims 22-25.

Owens *et al* teach the modification of murine antibodies such as a chimeric antibody, a single chain antibody, a Fab fragment, a F(ab')₂ fragment or a humanized antibody antibodies monoclonal antibody technology, chimeric, single chain, Fab fragments, and F(ab')₂. Owens *et al* further teach antibody fragments are the reagents of choice for some clinical applications (see the entire document).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce the monoclonal antibody taught by Bendayan as chimeric, humanized antibody, Fab and F(ab')₂ fragments taught by the Owens *et al*.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the antibody fragments are the reagents of choice for some clinical applications as taught by Owens *et al*.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the

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invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 16, 2006

Maher Haddad

Maher Haddad, Ph.D.

Patent Examiner

Technology Center 1600

Attachment I

GenCore version 5.1.8
Copyright (c) 1993 - 2006 Bioacceleration Ltd.

OM protein - protein search, using sw model

Run on: May 9, 2006, 10:53:35 ; Search time 14 Seconds
(without alignments)
2219.858 Million cell updates/sec

Title: US-10-634-905-2

Perfect score: 1705
Sequence: 1 MKSALFTRFFILLPWILVI.....EKNVLANEPKYHLDTVKIEV 323

Scoring table: BLOSUM62
Gapop 10.0 , Gapext 0.5

Searched: 283416 seqs, 96216763 residues

Total number of hits satisfying chosen parameters: 283416

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
Maximum Match 100%
Listing first 45 summaries

Database : FIR_80: *
1: pir1: *
2: pir2: *
3: pir3: *
4: pir4: *

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Match	Length	DB	ID	Description
1	1526.5	89.5	324	2	JG0163	glucuronyltransferase
2	777.5	45.6	347	2	JC7828	glucuronyltransferase
3	529.5	31.1	356	2	T27733	hypothetical prote
4	365	21.4	259	2	T20205	hypothetical prote
5	361	21.2	290	2	T24926	hypothetical prote
6	355	20.8	248	2	T20027	hypothetical prote
7	347.5	20.4	226	2	T20447	hypothetical prote
8	336	19.7	325	2	T24737	hypothetical prote
9	180	10.6	351	2	D84788	hypothetical prote
10	169	9.9	544	2	F85435	UDP-glucuronyltran
11	111	6.5	666	2	B70803	hypothetical prote
12	107	6.3	516	2	T49422	RAD57 related prot
13	102	6.0	786	1	A47547	serine proteinase
14	101	5.9	92	2	T29701	hypothetical prote
15	99.5	5.8	813	1	S33261	protein kinase lin
16	97	5.7	586	2	T29695	hypothetical prote
17	96	5.6	767	2	S41479	DNA-binding protei
18	96	5.6	2282	2	T24217	DNA-binding protei
19	94	5.5	1360	2	T32833	hypothetical prote
20	92	5.4	497	2	S22708	homeotic protein e
21	92	5.4	1396	2	A44453	translation initia
22	91.5	5.4	367	2	H83088	membrane-bound lyt
23	91.5	5.4	445	2	A75376	probable oligosacc
24	91	5.3	1466	2	T32422	hypothetical prote
25	90.5	5.3	285	2	S08491	hypothetical prote
26	90.5	5.3	520	1	F0LJGL	gag polyprotein -
27	90.5	5.3	1520	2	T00273	hypothetical prote
28	90.5	5.3	4135	2	T42629	tenascin-X - bovin
29	89.5	5.2	366	2	AG2060	hypothetical prote

30	89.5	5.2	497	2	F83634	hypothetical prote
31	89.5	5.2	591	2	G96734	spore coat protein
32	89	5.2	428	2	A83005	conserved hypothet
33	88.5	5.2	448	2	D87146	conserved hypothet
34	88.5	5.2	818	2	A59433	KIAA0672 protein l
35	88	5.2	727	2	AD1868	hypothetical prote
36	87.5	5.1	364	2	CB7455	alanine racemase l
37	87	5.1	1258	2	JC5765	inositol polyphosp
38	86	5.0	964	2	D59404	plectin isoform pl
39	85.5	5.0	370	2	AG0359	probable membrane-
40	85.5	5.0	1091	2	S33596	protein-tyrosine k
41	85.5	5.0	1892	2	T18314	hypothetical prote
42	85.5	5.0	4687	1	A39638	plectin - rat
43	85	5.0	1377	2	C65159	rhaA protein precu
44	84.5	5.0	147	2	S37485	gene mslg protein
45	84.5	5.0	264	2	AH2041	hypothetical prote

ALIGNMENTS

RESULT 1

JG0163
Glucuronyltransferase - rat
C:Species: Rattus norvegicus (Norway rat)
C:Date: 23-Jul-1999 #sequence_revision 23-Jul-1999 #text_change 09-Jul-2004
C:Accession: JG0163
R:Seiki, T.; Oka, S.; Terayama, K.; Imiya, K.; Kawasaki, T.
Biochem. Biophys. Res. Commun. 255, 182-187, 1999
A:Title: Molecular cloning and expression of a second glucuronyltransferase involved in
A:Reference number: JG0163; MUID:99185317; PMID:10082676
A:Accession: JG0163
A:Status: preliminary
A:Molecule type: DNA
A:Residues: 1-324 <SEI>
A:Cross-references: UNIPROT:Q9Z137; UNIPARC:UPI000012670D; DBJ:AB010441; NID:94519213;

Query Match 89.5%; Score 1526.5; DB 2; Length 324;
Best Local Similarity 89.8%; Pred. No. 5.8e-119;
Matches 291; Conservative 10; Mismatches 22; Indels 1; Gaps 1;

Qy	1	MKSALFTRFFILLPWILVIIMLDVTRRPVPLTPRPYFSPYAVGRCGRLPLRRGGPA	60
Db	1	MKSALCNRFILLPWILVIIMLDVDRPPAPQLTSRPYFSPHTVCGGSRVPLRRSSPG	60
Qy	61	H-GTQKENSRRPQPPQLPTIYAITPTYSRPVQKAEITLANTFRQVAQLHWILVDA	119
Db	61	RDAAEKRNESRPQLQPBPLTIYAITPTYSRPVQKAEITLANTFRQVAQLHWILVDR	120
Qy	120	AARSELVSRLARAGLPSTLHVPTPRYKRPGLPRATEQRNAGLAWLRQRHQHQAQPG	179
Db	121	ATRSSELVSSFLARAGLPNTHLVPTPRYKRPGLPRATEQRNAGLAWLRQRHQHQAQPG	180
Qy	180	VLFPADDDNTYLSLEFQEMRTRKVSVMVGLVGRRYRPLVNGKVGVWYTWGRDRP	239
Db	181	VLFPADDDNTYLSLEFQEMRTRKVSVMVGLVGRRYRPLVNGKVGVWYTWGRDRP	240
Qy	240	PAIDMAGFVSLQVILSNPKAVFKRGSGQMSDFLKQITTYEELEPKANNCTKVLVM	299
Db	241	PAIDMAGFVSLQVILSNPKAVFKRGSGQMSDFLKQITTYEELEPKANNCTKVLVM	300
Qy	300	HTRTEKVNLANEPKYHLDTVKIEV	323
Db	301	HTRTEKVNLANEPKYHMDTVNIEV	324

RESULT 2

JC7828
glucuronyltransferase-P, long form - mouse
C:Species: Mus musculus (house mouse)
C:Date: 03-Jun-2002 #sequence_revision 03-Jun-2002 #text_change 09-Jul-2004
C:Accession: JC7828
R:Yamamoto, S.; Oka, S.; Saito-Ohara, F.; Inazawa, J.; Kawasaki, T.